REMARKS

Applicant has amended his claims to better clarify the invention. Claim 1 is amended herein to recite, *inter alia*, providing a racemic mixture comprising *d-threo*-methylphenidate and *l-threo*-methylphenidate and treating said racemic mixture with a first optically active acid to obtain a second mixture of *d-threo*-methylphenidate and *l-threo*-methylphenidate from said racemic mixture, wherein said second mixture comprises *d-threo*-methylphenidate having greater than a 90 percent enantiomeric excess, wherein said first optically active acid does not comprise *l*-fenchyloxyacetic acid. Support can be found in the Specification on Page 6 at Lines 9 - 12, on Page 8 at Lines 6 through 17, and in FIG. 2 at steps 210 and 220.

Claims 6 and 8 are amended herein to recite treating a racemic mixture of *d-threo*-methylphenidate and *l-threo*-methylphenidate with dibenzoyl-L-tartrate. Support can be found in the Specification on Page 6 at Lines 9 - 12, on Page 8 at Lines 6 through 17, and in FIG. 2 at steps 210 and 220.

No new matter has been entered. Reexamination and reconsideration of the application, as amended, is respectfully requested.

Claims 1-3, 6-9, and 12, stand rejected under 35 USC 103(a) as being unpatentable over Zavareh (U.S. Pat. No. 6,121,453) in view of Harris et al. (U.S. Pat. No. 6,531,489), Leffler [Organic Synthesis, Coll. Vol. 3, p. 544 (1955);Vol. 23, p. 52 (1943)], DBGET Factsheet for Compound C02344, and Brunson (U.S. Pat. No. 9,920,160).

Zavareh teaches resolving dl-threo-methylphenidate using (-)-menthoxyacetic acid. Col. 1 at Lines 34-36; Col. 2 at Lines 28-30. Zavareh nowhere teaches use of *l*-fenchyloxyacetic acid to resolve dl-threo-methylphenidate, as recited in Applicant's claims 1,

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6, and 12, as amended herein.

The Examiner posits that (-)-menthoxyacetic acid and *l*-fenchyloxyacetic acid have "similar chemical structures", and therefore, it would have been obvious to "substitute one oxyacetic acid for another." May 2, 2006 Office Action at Page 3. Applicant respectfully disagrees. As a preliminary matter, resolving dl-threo-methylphenidate is not an easy task. The review article by Mahavir Prashad entitled "Approaches to the Preparation of Enantiomerically Pure (2R,2'R)-(+)-threo-Methylphenidate Hydrochloride and referenced by the Examiner teaches, inter alia, "Ritalinic acid itself did not undergo any effective degree of resolution with any of a wide range of resolving agents." Prashad at Page 383. Moreover, Applicant unsuccessfully attempted to resolve dl-threo-methylphenidate using *d*-10-camphor sulfonic acid, L-aspartic acid, Deoxycholic acid, D-pyrrolidine carboxylic acid, (+)-Mandelic acid, and (-)-borneoloxyacetic acid. *See*, George R. Krsek Declaration at Paragraphs 2, 3, and 4.

Regarding the Examiner's thesis that menthoxyacetic acid and *l*-fenchyloxyacetic acid comprise similar chemical structures, (-) -Menthoxyacetic acid comprises a substituted cyclohexane structure while *l*-fenchyloxyacetic acid comprises a substituted bicyclo[2.2.1]heptane structure. Applicant respectfully submits that (-)-menthoxyacetic acid and *l*-fenchyloxyacetic acid clearly comprise dissimilar chemical structures.

Moreover, even if (-)-menthoxyacetic acid and *l*-fenchyloxyacetic acid did comprise similar chemical structures, Applicant further respectfully submits that one cannot *a priori* predict the efficacy of an optically active oxyacetic acid to resolve dl-threo-methylphenidate based upon the chemical structure of that oxyacetic acid. To illustrate, Applicant

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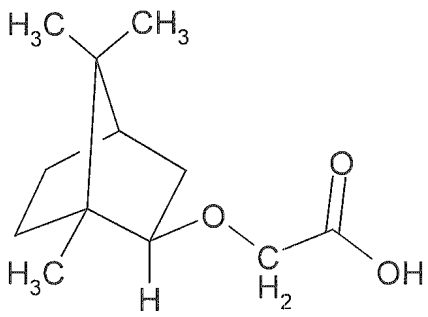
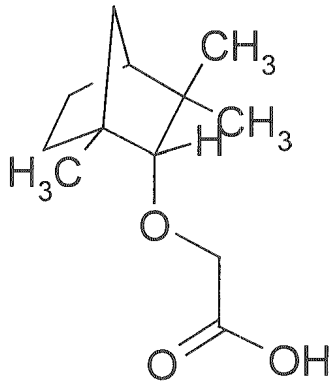
unsuccessfully attempted to resolve dl-methylphenidate using (-)-borneoloxyacetic acid. *See*, George R. Krsek Declaration ("Krsek") at Paragraph 4.



(-)-Borneoloxyacetic acid



l-Fenchyloxyacetic acid

Applicant trusts the Examiner will appreciate that both (-)-borneoloxyacetic acid and *l*-fenchyloxyacetic acid comprise substituted bicyclo[2.2.1]heptane structures. As described and claimed in the pending Application, Applicant successfully used *l*-fenchyloxyacetic acid to resolve dl- threo-methylphenidate to give d-threo-methylphenidate. On the other hand, use of (-)-borneoloxyacetic acid was not successful. *See*, Krsek at Paragraph 4. This being the case, Applicant respectfully submits that one could not *a priori* predict the efficacy of *l*-fenchyloxyacetic acid to resolve dl-threo-methylphenidate based upon the teachings of

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Zavareh. This being the case, Applicant further respectfully submits that his successful use of to resolve dl-methylphenidate is non-obvious over the teachings of Zavareh.

Zavareh actually teaches away from Applicant's claims 1, 6, and 12, as amended herein. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference . . . would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed.Cir. 1994).

Zavareh teaches, *inter alia*, that his invention is "based upon the discovery that racemic threo methylphenidate can be resolved using inexpensive (-)-menthoxyacetic acid." Col. 1 at Lines 34-36. As detailed in the Krsek Declaration, *l*-fenchyloxyacetic acid is more expensive than (-)-menthoxyacetic acid. The Examiner posits that it would be obvious from the teachings of Zavareh to resolve dl-threo-methylphenidate using even less expensive oxyacetic acids.

Leffler teaches a method to prepare (-)-menthoxyacetic acid from (-)-menthol and chloroacetic acid. Applicant prepared *l*-fenchyloxyacetic acid from *l*-fenchyl alcohol and chloroacetic acid. *See*, Application on Page 9 at Line 16 through Page 10 at Line 20. Referring now to Attachments "A" and "B" to the Krsek Declaration, the cost to prepare (-)-menthloxyacetic acid using the synthetic method of Leffler, and using (-)-menthyl alcohol purchased from Aldrich Chemical Company, would be twenty cents ($0.20) per gram. *See*, Krsek at Paragraphs 5, 6, 8, 9, 11, and 12.

On the other hand, the cost to prepare *l*-fenchyloxyacetic acid using *l*-fenchyl alcohol purchased from Aldrich Chemical Company, would be twenty-eight cents ($0.28) per gram. *See*, Krsek at Paragraphs 5, 6, 7, 10, 13, and 14. This being the case, *l*-fenchyloxyacetic acid costs eighty percent (80%) more than does (-)-menthoxyacetic acid.

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Using the Examiner's logic, one of ordinary skill in the art following the teachings of Zavareh would find motivation to use an optically active oxyacetic acid that costs less than (-)-menthoxyacetic acid. This being the case, one or ordinary skill in the art following the teachings of Zavareh would find no motivation to prepare and use an optically-active oxyacetic acid, such as *l*-fenchyloxyacetic acid, costing eighty percent more than (-)-menthoxyacetic acid. Once again, Applicant respectfully submits that Zavareh neither teaches or suggests use of *l*-fenchyloxyacetic acid to resolve dl-threo-methylphenidate.

"To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP 2143.03; *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Neither Zavareh, nor Harris et al., nor Leffler, nor the DBGET Factsheet, nor Brunson, singly or in combination, teach or suggest use of *l*-fenchyloxyacetic acid to resolve dl-threo-methylphenidate, as recited in Applicant's claims 1, 6, and 12, as amended herein.

"If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious." MPEP 2143.03; *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed.Cir. 1988). Claims 2-5 depend, directly or indirectly, from claim 1. Under 35 U.S.C. § 112, fourth paragraph, "a claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." Therefore claims 2-6, as amended herein, include all the elements of claim 1, as amended herein. Applicant respectfully submits that claim 1, as amended herein, is non-obvious over any combination of the teachings of Zavareh, Harris et al., Leffler, the DBGET Fact sheet, and/or Brunson. This being the case, Applicants further respectfully submit that claims 2-6, as amended herein, are non-obvious over

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the combined teachings of Zavareh, Harris et al., Leffler, the DBGET Factsheet, and/or Brunson.

Claims 8-12 depend, directly or indirectly, from claim 6. Under 35 U.S.C. § 112, fourth paragraph, "a claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." Therefore claims 8-12, as amended herein, include all the elements of claim 6, as amended herein. Applicant respectfully submits that claim 6, as amended herein, is non-obvious over any combination of the teachings of Zavareh, Harris et al., Leffler, the DBGET Fact sheet, and/or Brunson. This being the case, Applicants further respectfully submit that claims 8-12, as amended herein, are non-obvious over the combined teachings of Zavareh, Harris et al., Leffler, the DBGET Fact sheet, and/or Brunson.

Having dealt with all of the outstanding objections and/or rejections of the claims, Applicants submit that the application as amended is in condition for allowance, and an allowance at an early date is respectfully solicited. In the event there are any fee deficiencies or additional fees are payable, please charge them, or credit an overpayment, to our Deposit Account No. 502262.

Respectfully submitted,

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CERTIFICATE OF ELECTRONIC FILING

I hereby certify that on this 2nd day of November, 2006, the Amendment A is being filed via the Web Enabled Patent Filing System (EFT-WEB).

By: _____

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